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## **EXAMINER'S AMENDMENT AND REASONS FOR ALLOWANCE**

### **Informal Matters**

1. The response and remarks filed 01 April 2009 to Final Office Action mailed 06 January 2009 are acknowledged and entered.

### **Withdrawal of Rejections**

2. In consideration of response and remarks filed 01 April 2009 to the Office Action mailed 06 January 2009, following objections/rejections in the -Office Action mailed 06 January 2009 are hereby withdrawn:

- Lack of written description rejection to Claims 5 and 7 under 35 U.S.C. §112, 1<sup>st</sup> paragraph; and
- Obviousness rejection to Claims 5, 7 and 31 under 35 U.S.C. §103(a) as obvious and unpatentable over the combined teachings from Ford et al. (US Patent 6,497,870 B1) in view of Hancock et al (US Patent 6,040,435) and further in view of Aley et al (Infection and Immunity, 1994, Volume 62, pages 5397-5403).

### **Claims Status**

3. Claims 8-16 and 29-30 currently remain cancelled.
4. Claims 1-7, 17-28 and 31 are currently pending.
5. Claims 1-4 and 17-28 remain withdrawn.
6. Claim 5 has currently been amended.
7. Claims 5-7 and 31 are currently under examination.

### ***Restriction/Election***

8. In accordance with literature search, re-consideration of pending Claims (i.e., Claims 1-7, 17-28 and 31) and those currently under examination (i.e., Claims 5-7 and 31), and according to the provisions under 37 C.F.R. §1.41; Claims 1-4 and 17-28 previously withdrawn from consideration as a result of a restriction requirement (see, Applicants' response filed 25 May 2006 in response to Office Action mailed

04 May 2006), are now subject to being rejoined. Claims 1-4 and 17-28 are hereby rejoined with Claims 5-7 and 31 and fully examined for patentability under 37 C.F.R. §1.104.

9. Claims 1-7, 17-28 and 31 are currently pending, and are examined on merits.

### **Examiner's Amendment**

10. An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicants, an amendment may be filed as provided by 37 C.F.R. §1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this Examiner's amendment was given in a telephone interview on 16 April 2009 with Mr. Norman D. Hanson, Applicants' Representative.

#### **In the Claims**

The following listing of claims will replace all prior versions and listings of claims in the application:

#### **LISTING OF CLAIMS:**

Claim 1. (Original) A method for identifying an antimicrobial peptide which binds to an infective stage microorganism and damages said microorganism comprising:

(a) contacting an infective stage microorganism with a plurality of non-identical peptides of claim 5,

(b) identifying peptides that bind to the microorganism, and

(c) assaying the peptides identified in (b) for capacity to damage the microorganism,

wherein damage to said microorganism by a peptide of (c) indicates that the peptide of (c) is an antimicrobial peptide which binds to an infective stage microorganism and damages said microorganism.

Claim 2. (Original) The method of claim 1, wherein the plurality of peptides is expressed on a bacteriophage.

Claim 3. (Original) The method of claim 1, comprising contacting said microorganism with a library of synthetic peptides.

Claim 4. (Original) The method of claim 1, wherein the microorganism is a protozoa, a fungus, a ~~gram~~ Gram positive bacterium or a ~~gram~~ Gram negative bacterium.

Claim 5. (Previously Presented) An isolated antimicrobial peptide consisting of from 10 to 12 amino acids of which 7 out of said 10 to 12 amino acids are hydrophobic residues, 3 of said 10 to 12 amino acids are basic residues and at least one of said 10 to 12 amino acids is histidine (His), glutamic acid (Glu) or serine (Ser), with the proviso that two of the hydrophobic amino acids must be tryptophan (Trp) residues and said two tryptophan residues are adjacent tryptophans.

Claim 6. (Previously Presented) The isolated antimicrobial peptide of claim 5, comprising the amino acid sequence set forth in SEQ ID NO: 1.

Claim 7. (Original) The isolated antimicrobial peptide of claim 5, wherein said peptide is amidated, carboxymethylated or cyclized.

Claims 8-16 (Canceled)

Claim 17. (Currently Amended) A method for preventing growth, inhibiting growth or decreasing viability of a microorganism comprising contacting said microorganism with an effective amount of the ~~polypeptide~~ peptide of Claim 5, sufficient to prevent growth, to inhibit growth or to decrease viability of said microorganism.

Claim 18. (Original) The method of claim 17, wherein said microorganism is a protozoa or a fungus.

Claim 19. (Original) The method of claim 17, wherein said microorganism is present in an environment that is capable of sustaining viability of the microorganism.

Claim 20. (Currently Amended) The method of claim 19, wherein said environment is a water sample, a food product, a feed, an animal, or a plant.

Claim 21. (Currently Amended) The method of claim 18, wherein the protozoa is an ~~Eimeria~~ Eimeria (E.) species, a ~~Toxoplasma~~ Toxoplasma (T.) species, a ~~Crithidia~~ Crithidia (Cr.) species, or a ~~Trypanosoma~~ Trypanosoma (Tr.) species.

Claim 22. (Currently Amended) The method of claim 18, wherein the fungus is selected from the group consisting of ~~Candida albicans, Aspergillus nidulans, Colletotrichum gossypii, Alternaria macrospora, Bipolaris sorokiniana, Dreschlera tritici, Phoma sorghina, Microdochium oryzae, Bipolaris oryzae, Pyricularia grisea, Colletotrichum gloeosporioides, Rhizoctonia solani and Fusarium solani~~ Candida albicans or Aspergillus nidulans, Colletotrichum gossypii, Alternaria macrospora, Bipolaris sorokiniana, Dreschlera tritici, Phoma sorghina, Microdochium oryzae, Bipolaris oryzae, Pyricularia grisea, Colletotrichum gloeosporioides, Rhizoctonia solani and Fusarium solani.

Claim 23. (Currently Amended) The method of claim 18, wherein the protozoa is selected from the group consisting of ~~E. acervulina or E. tenella~~ E. acervulina or E. tenella.

Claim 24. (Original) A method for treating an organism infected with a pathogenic microorganism comprising administering an effective amount of the isolated antimicrobial peptide of claim 5 to said organism sufficient to alleviate said infection.

Claim 25. (Currently amended) The method of claim 24, wherein said organism is a bird, a mammal, or a plant.

Claim 26. (Currently amended) The method of claim 24, wherein the pathogenic microorganism is a fungus, or a protozoa.

Claim 27. (Currently Amended) The method of claim 26, wherein the protozoa is an ~~Eimeria~~ Eimeria, or a ~~Toxoplasma~~ Toxoplasma.

Claim 28. (Currently Amended) The method of claim 26, wherein the fungus is selected from the group consisting of ~~Candida albicans or Aspergillus nidulans, Colletotrichum gossypii, Alternaria macrospora, Bipolaris sorokiniana, Dreschlera tritici, Phoma sorghina, Microdochium oryzae, Bipolaris oryzae, Pyricularia grisea, Colletotrichum~~

gloeosporioides, Rhizoctonia solani and Fusarium solani Candida albicans or Aspergillus nidulans, Colletotrichum gossypii, Alternaria macrospora, Bipolaris sorokiniana, Dreschslem tritiei, Phoma sorghina, Microdochium oryzae, Bipolaris oryzae, Pyricularia grisea, Colletotrichum gloeosporioides, Rhizoctonia solani and Fusarium solani.

Claims 29-30. (Canceled)

Claim 3I. (Previously Presented) The isolated peptide of claim 5, consisting of the amino acid sequence set forth in SEQ ID NO: 1, 2, 3, or 4.

### Examiner's Reasons for Allowance

11. The following is Examiner's statement of reasons for allowance:

The closest art references are:

- Nagpal et al (1999. Structure-Function Analysis of Tritrypticin, an Antibacterial Peptide of Innate Immune Origin. Journal of Biological Chemistry, Volume 274, Number 33, Pages 32296-32304), published 13 August 1999.

Nagpal et al., teach a 12 (dodecamer) amino acid long antimicrobial peptide having 7 hydrophobic residues, 3 basic residues, wherein two of the hydrophobic tryptophan (Trp) are adjacent (See Table 1). Nagpal et al., however, do not teach a glutamic acid (Glu), histidine (His) or serine (Ser) residues in said dodecamer antimicrobial peptide.

- U. S. Patent 7,214,766 B2 issued 08 May 2007 to Everett et al.

Everett et al., teach a 12 (i.e., dodecamer) amino acid long antimicrobial peptide. Everett et al., however, do not teach two adjacent Trp residues, glutamic acid (Glu), histidine (His) or serine (Ser) residues in said dodecamer antimicrobial peptide.

- U. S. Patent 6, 835, 536 B2 issued 28 December 2004 to Krieger et al.

Krieger et al., teach a number of 12 (i.e., dodecamer) amino acid long antimicrobial peptide having hydrophobic residues, 3 basic residues, wherein two of the hydrophobic tryptophan (Trp) are adjacent (See, e.g., Column 65, SEQ ID No. 58; or Column 89, SEQ ID No. 120). Krieger et al., however, do not teach glutamic acid

(Glu), histidine (His) or serine (Ser) residues in said dodecamer antimicrobial peptide.

Thus, none of the references cited *supra* either separately or in combination teach each and every feature of the claimed invention. Consequently, the instantly claimed invention in Claims 1-7, 17-28 and 31 is neither anticipated, nor is obvious over the combined teachings of any, or all above-cited art references.

12. Any comments considered necessary by applicants must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### Conclusion

13. Claims 1-7, 17-28 and 31 are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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23 April 2009

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